IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACORDA THERAPEUTICS, INC. and ALKERMES PHARMA IRELAND LIMITED,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

COMPLAINT

Acorda Therapeutics, Inc. ("Acorda") and Alkermes Pharma Ireland Limited ("Alkermes" and together with Acorda, "Plaintiffs"), for their Complaint against Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendant"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Plaintiffs against Teva for patent infringement of United States Patent Nos. 5,540,938 (the "'938 patent"), 8,007,826 (the "'826 patent"), 8,354,437 (the "'437 patent"), 8,440,703 (the "'703 patent") and 8,663,685 (the "'685 patent") (collectively, the "Ampyra® Patents").

2. This action arises out of Teva's filing of Abbreviated New Drug Application ("ANDA") No. 206854 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Acorda's flagship drug product Ampyra®, prior to the expiration of the Ampyra® Patents.

THE PARTIES

3. Acorda is a corporation organized under the laws of the State of Delaware and has its principal place of business located at 420 Saw Mill River Road, Ardsley, New York 10502.

Acorda is engaged in the research, development, and sale of biotech and pharmaceutical products. Acorda invests extensively in designing and developing new and innovative therapies to restore neurological function and improve the lives of people with multiple sclerosis ("MS"), spinal cord injuries and other disorders of the nervous system. Ampyra® is the only treatment shown to improve walking in people with MS, which was demonstrated by an increase in walking speed.

4. Alkermes is an Irish corporation (company number 448848) having a principal place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland.

5. Alkermes is the assignee of the '938 patent. Acorda is the exclusive licensee in the U.S. to package, use, import, export, promote, distribute, offer for sale, sell and otherwise exploit the '938 patent for oral prescription medicine for the treatment of MS in humans. Acorda also has the right to initiate and prosecute legal action for infringement by a third-party of the '938 patent.

6. Acorda has all right, title, and interest in the '826 patent, '437 patent, '703 patent, and '685 patent, and the right to sue for infringement thereof.

7. On information and belief, defendant Teva Pharmaceuticals USA, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Teva.

10. This Court has personal jurisdiction over Teva because it is a corporation organized and existing under the laws of the State of Delaware.

11. On information and belief, Teva has previously admitted in other civil actions that it is subject to personal jurisdiction in Delaware, including, for example, in *Genzyme Corporation et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 1:13-cv-01506-GMS, (D. Del. May 15, 2014) (Doc. 60, ¶7).

12. Also, this Court has personal jurisdiction over Teva by virtue of the fact it, *inter alia*, has committed — or aided, abetted, induced, contributed to, or participated in the commission of — the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Acorda, a Delaware corporation, and to Alkermes.

13. On information and belief, Teva is in the business of, among other things, formulating, developing, manufacturing, packaging, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in Delaware.

14. On information and belief, Teva regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed by Teva or its affiliates and agents, in Delaware, demonstrating that Teva has continuous and systemic contacts with Delaware.

15. On information and belief, Teva is registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed "Pharmacy - Wholesale" (License Nos. A4-0001468, A4-0001681 and A4-0001447) and "Distributor/Manufacturer CSR" (License Nos. DM-0006546 and DM-0007115).

16. On information and belief, Teva is registered to do business with the Delaware Department of State, Division of Corporations.

17. On information and belief, Teva has designated a registered agent in Delaware as Corporate Creations Network Inc., 3411 Silverside Rd. #104 Rodney Building, Wilmington, Delaware 19810.

18. On information and belief, if ANDA No. 206854 is approved, the dalfampridine extended release tablets described in Teva's ANDA No. 206854 (the "Teva Generic Tablets"), which are accused of infringing the Ampyra® Patents, will, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which will have a substantial effect on Delaware.

19. Teva knows and intends that Teva Generic Tablets will be distributed and sold in the United States, including in Delaware.

20. On information and belief, Teva has previously availed itself of this forum by initiating civil actions in this jurisdiction, including, for example, *Teva Pharmaceuticals USA Inc. et al. v. Forest Laboratories Inc.*, C.A. No. 1:13-cv-02002-GMS (D. Del. Dec. 5, 2013) (Doc. 1) and *Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA Inc. v. Torrent Pharmaceuticals Ltd. et al.*, C.A. No. 1:07-cv-00332-GMS (D. Del. May 25, 2007) (Doc. 1).

21. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

The ’938 Patent

22. On July 30, 1996, the United States Patent and Trademark Office (“USPTO”) issued the ’938 patent, titled “Formulations and Their Use in the Treatment of Neurological Diseases.” The ’938 patent is duly and legally assigned to Alkermes. Acorda is the exclusive licensee in the U.S. to package, use, import, export, promote, distribute, offer for sale, sell and otherwise exploit the ’938 patent for oral prescription medicine for the treatment of MS in humans. Acorda also has the right to initiate and prosecute legal action for infringement by a third-party of the ’938 patent. A copy of the ’938 patent is attached hereto as Exhibit A.

The ’826 Patent

23. On August 30, 2011, the USPTO issued the ’826 patent, titled “Sustained Release Aminopyridine Composition.” The ’826 patent is duly and legally assigned to Acorda. A copy of the ’826 patent is attached hereto as Exhibit B.

The ’437 Patent

24. On January 15, 2013, the USPTO issued the ’437 patent, titled “Method of Using Sustained Release Aminopyridine Compositions.” The ’437 patent is duly and legally assigned to Acorda. A copy of the ’437 patent is attached hereto as Exhibit C.

The ’703 Patent

25. On May 14, 2013, the USPTO issued the ’703 patent, titled “Methods of Using Sustained Release Aminopyridine Compositions.” The ’703 patent is duly and legally assigned to Acorda. A copy of the ’703 patent is attached hereto as Exhibit D.

The ’685 Patent

26. On March 4, 2014, the USPTO issued the ’685 patent, titled “Sustained Release Aminopyridine Composition.” The ’685 patent is duly and legally assigned to Acorda. A copy of the ’685 patent is attached hereto as Exhibit E.

Orange Book Listing for Ampyra®

27. Acorda holds an approved New Drug Application (“NDA”), No. 022250, for the use of 10 mg dalfampridine extended release tablets to improve walking in patients with multiple sclerosis, which Acorda sells under the registered name Ampyra®.

28. The use of Ampyra® to improve walking in patients with MS is covered by the Ampyra® Patents.

29. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the Ampyra® Patents are listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) for improvement of walking in patients with MS.

30. The Orange Book lists the expiration dates for the ’938 patent as July 30, 2018, the ’826 patent as May 26, 2027, the ’437 patent as December 22, 2026, the ’703 patent as April 8, 2025, and the ’685 patent as January 18, 2025.

TEVA’S ANDA

31. By letter dated July 11, 2014 (the “Teva Notice Letter”) and received by Plaintiffs on July 14, 2014, Teva Pharmaceuticals USA, Inc. notified Plaintiffs that it had filed ANDA No. 206854 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act (“FDCA”) to market and sell Teva Generic Tablets – generic copies of Ampyra® (10 mg dalfampridine extended release tablets) – prior to the expiration of the Ampyra® Patents.

32. The Teva Notice Letter asserts that ANDA No. 206854 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and that each of the Ampyra® Patents are "not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of" the Teva Generic Tablets.

33. The Teva Notice Letter also states that ANDA No. 206854 was submitted to the FDA and contains a Paragraph IV certification seeking "approval to engage in the commercial manufacture, use, or sale of [Teva Generic Tablets] prior to expiration of [the Ampyra® Patents]."

34. Upon information and belief, Teva will distribute the Teva Generic Tablets in the United States.

COUNT I
(Infringement of the '938 Patent)

35. The allegations of paragraphs 1-34 above are repeated and re-alleged as if set forth fully herein.

36. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva's filing of ANDA No. 206854 seeking approval to market Teva Generic Tablets is an act of infringement of one or more claims of the '938 patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206854 be a date which is not earlier than the expiration date of the '938 patent.

37. Teva had knowledge of the '938 patent when it submitted ANDA No. 206854 to the FDA.

38. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva Generic Tablets with the proposed labeling. The

use of Teva Generic Tablets in accordance with and as directed by Teva's proposed labeling would infringe one or more claims of the '938 patent.

39. Upon information and belief, Teva intends to actively induce infringement of one or more claims of the '938 patent.

40. Upon information and belief, Teva knows that Teva Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '938 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

41. Upon information and belief, Teva intends to contribute to the infringement of one or more claims of the '938 patent.

42. The foregoing actions by Teva constitute and/or would constitute infringement of one or more claims of the '938 patent, active inducement of infringement of one or more claims of the '938 patent, and/or contribution to the infringement by others of one or more claims of the '938 patent.

43. Plaintiffs will be substantially and irreparably harmed if Teva is not enjoined from infringing the '938 patent. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '826 Patent)

44. The allegations of paragraphs 1-43 above are repeated and re-alleged as if set forth fully herein.

45. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva's filing of ANDA No. 206854 seeking approval to market Teva Generic Tablets is an act of infringement of one or more claims of the '826 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including,

inter alia, an order of this Court that the effective date of approval for ANDA No. 206854 be a date which is not earlier than the expiration date of the '826 patent.

46. Teva had knowledge of the '826 patent when it submitted ANDA No. 206854 to the FDA.

47. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva Generic Tablets with the proposed labeling. The use of Teva Generic Tablets in accordance with and as directed by Teva's proposed labeling would infringe one or more claims of the '826 patent.

48. Upon information and belief, Teva intends to actively induce infringement of one or more claims of the '826 patent.

49. Upon information and belief, Teva knows that Teva Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '826 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

50. Upon information and belief, Teva intends to contribute to the infringement of one or more claims of the '826 patent.

51. The foregoing actions by Teva constitute and/or would constitute infringement of one or more claims of the '826 patent, active inducement of infringement of one or more claims of the '826 patent, and/or contribution to the infringement by others of one or more claims of the '826 patent.

52. Acorda will be substantially and irreparably harmed if Teva is not enjoined from infringing the '826 patent. Acorda has no adequate remedy at law.

COUNT III
(Infringement of the ’437 Patent)

53. The allegations of paragraphs 1-52 above are repeated and re-alleged as if set forth fully herein.

54. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva’s filing of ANDA No. 206854 seeking approval to market Teva Generic Tablets is an act of infringement of one or more claims of the ’437 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206854 be a date which is not earlier than the expiration date of the ’437 patent.

55. Teva had knowledge of the ’437 patent when it submitted ANDA No. 206854 to the FDA.

56. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva Generic Tablets with the proposed labeling. The use of Teva Generic Tablets in accordance with and as directed by Teva’s proposed labeling would infringe one or more claims of the ’437 patent.

57. Upon information and belief, Teva intends to actively induce infringement of one or more claims of the ’437 patent.

58. Upon information and belief, Teva knows that Teva Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the ’437 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

59. Upon information and belief, Teva intends to contribute to the infringement of one or more claims of the ’437 patent.

60. The foregoing actions by Teva constitute and/or would constitute infringement of one or more claims of the ’437 patent, active inducement of infringement of one or more claims of the ’437 patent, and/or contribution to the infringement by others of one or more claims of the ’437 patent.

61. Acorda will be substantially and irreparably harmed if Teva is not enjoined from infringing the ’437 patent. Acorda has no adequate remedy at law.

COUNT IV
(Infringement of the ’703 Patent)

62. The allegations of paragraphs 1-61 above are repeated and re-alleged as if set forth fully herein.

63. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva’s filing of ANDA No. 206854 seeking approval to market Teva Generic Tablets is an act of infringement of one or more claims of the ’703 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206854 be a date which is not earlier than the expiration date of the ’703 patent.

64. Teva had knowledge of the ’703 patent when it submitted ANDA No. 206854 to the FDA.

65. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva Generic Tablets with the proposed labeling. The use of Teva Generic Tablets in accordance with and as directed by Teva’s proposed labeling would infringe one or more claims of the ’703 patent.

66. Upon information and belief, Teva intends to actively induce infringement of one or more claims of the ’703 patent.

67. Upon information and belief, Teva knows that Teva Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the ’703 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

68. Upon information and belief, Teva intends to contribute to the infringement of one or more claims of the ’703 patent.

69. The foregoing actions by Teva constitute and/or would constitute infringement of one or more claims of the ’703 patent, active inducement of infringement of one or more claims of the ’703 patent, and/or contribution to the infringement by others of one or more claims of the ’703 patent.

70. Acorda will be substantially and irreparably harmed if Teva is not enjoined from infringing the ’703 patent. Acorda has no adequate remedy at law.

COUNT V
(Infringement of the ’685 Patent)

71. The allegations of paragraphs 1-70 above are repeated and re-alleged as if set forth fully herein.

72. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva’s filing of ANDA No. 206854 seeking approval to market Teva Generic Tablets is an act of infringement of one or more claims of the ’685 patent entitling Acorda to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 206854 be a date which is not earlier than the expiration date of the ’685 patent.

73. Teva had knowledge of the ’685 patent when it submitted ANDA No. 206854 to the FDA.

74. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva Generic Tablets with the proposed labeling. The use of Teva Generic Tablets in accordance with and as directed by Teva's proposed labeling would infringe one or more claims of the '685 patent.

75. Upon information and belief, Teva intends to actively induce infringement of one or more claims of the '685 patent.

76. Upon information and belief, Teva knows that Teva Generic Tablets and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '685 patent and that the ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

77. Upon information and belief, Teva intends to contribute to the infringement of one or more claims of the '685 patent.

78. The foregoing actions by Teva constitute and/or would constitute infringement of one or more claims of the '685 patent, active inducement of infringement of one or more claims of the '685 patent, and/or contribution to the infringement by others of one or more claims of the '685 patent.

79. Acorda will be substantially and irreparably harmed if Teva is not enjoined from infringing the '685 patent. Acorda has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. A judgment that Teva's submission of ANDA No. 206854 was an act of infringement and that Teva's making, using, offering to sell, selling or importing Teva Generic

Tablets prior to the expiration of the Ampyra® Patents will infringe, actively induce infringement and/or contribute to the infringement of each of the Ampyra® Patents;

B. A judgment that the effective date of any FDA approval for Teva to make, use offer for sale, sell, market, distribute, or import the Teva Generic Tablets be no earlier than the dates on which the Ampyra® Patents expire, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

C. A permanent injunction enjoining Teva, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing the Teva Generic Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the Ampyra® Patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

E. An award of Plaintiffs' costs and expenses in this action;

F. Such further and additional relief as this Court deems just and proper.

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